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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,751	07/02/2001	Wei Wang	DX0882XK	7429

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DNAX Research Institute
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EXAMINER

BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/16/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,751

Applicant(s)

WANG ET AL.

Examiner

Bridget E. Bunner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4 and 22-23 drawn to a method of modulating movement of a cell within or to the skin of a mammal, said method comprising administering to said mammal an effective amount of an antagonist of CTACK, classification dependent upon antagonist.
 - II. Claims 1-4 and 22-23 drawn to a method of modulating movement of a cell within or to the skin of a mammal, said method comprising administering to said mammal an effective amount of an antagonist of Vic, classification dependent upon antagonist.
 - III. Claims 1 and 5-8, drawn to a method of modulating movement of a cell within or to the skin of a mammal, said method comprising administering to said mammal an effective amount of an agonist of CTACK, classified in class 514, subclass 2.
 - IV. Claims 1 and 5-8, drawn to a method of modulating movement of a cell within or to the skin of a mammal, said method comprising administering to said mammal an effective amount of an agonist of Vic, classified in class 514, subclass 2.
 - V. Claims 9-11, drawn to a method of purifying a population of cells, said method comprising contacting cells with CTACK, thereby resulting in the identification of cells expressing a receptor for said CTACK, classified in class 435, subclass 325.
 - VI. Claims 9-11, drawn to a method of purifying a population of cells, said method comprising contacting cells with Vic, thereby resulting in the identification of cells expressing a receptor for said Vic, classified in class 435, subclass 325.
 - VII. Claims 12-13, drawn to a method of producing a ligand:receptor complex comprising contacting mammalian CTACK with a GPR2 receptor, classified in class 435, subclass 7.1.
 - VIII. Claims 12-13, drawn to a method of producing a ligand:receptor complex comprising contacting mammalian Vic with a GPR2 receptor, classified in class 435, subclass 7.1.
 - IX. Claims 14, drawn to a method of modulating physiology or development of a GPR2 expressing cell comprising contacting said cell to an agonist of a mammalian CTACK, classified in class 435, subclass 375.

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- X. Claim 14, drawn to a method of modulating physiology or development of a GPR2 expressing cell comprising contacting said cell to an agonist of a mammalian Vic, classified in class 435, subclass 375.
- XI. Claims 14-16, drawn to a method of modulating physiology or development of a GPR2 expressing cell comprising contacting said cell to an antagonist of a mammalian CTACK, classified in class 435, subclass 375.
- XII. Claims 14-16, drawn to a method of modulating physiology or development of a GPR2 expressing cell comprising contacting said cell to an antagonist of a mammalian Vic, classified in class 435, subclass 375.
- XIII. Claims 17-18, drawn to a method of testing a compound for ability to affect GPR2 receptor-ligand interaction, said method comprising comparing the interaction of GPR2 with CTACK, classified in class 435, subclass 7.1.
- XIV. Claims 17-18, drawn to a method of testing a compound for ability to affect GPR2 receptor-ligand interaction, said method comprising comparing the interaction of GPR2 with Vic, classified in class 435, subclass 7.1.
- XV. Claim 19, drawn to a primate GPR2, classified in class 530, subclass 350.
- XVI. Claim 20, drawn to a nucleic acid encoding a primate GPR2, classified in class 535, subclass 23.1.
- XVII. Claim 21, drawn to an antibody which binds selectively to a primate GPR2, classified in class 530, subclass 387.1.
- XVIII. Claim 22-23, drawn to a method of treating a patient suffering from a skin disorder comprising administering an effective amount of an antagonist against GPR2.

The inventions are distinct, each from the other because of the following reasons:

- a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions I-XIV and XVIII are different methods because they require different ingredients, process steps, and endpoints. Groups I-XIV and XVIII are different methods

requiring different method steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of blocking movement of a cell within or to the skin of a mammal and efficacy of therapy of administration of an antagonist of CTACK, which is not required by the other inventions. Invention II requires search and consideration of blocking movement of a cell within or to the skin of a mammal and efficacy of therapy of administration of an antagonist of Vic, which is not required by the other inventions. Invention III requires search and consideration of attracting movement of a cell within or to the skin of a mammal and efficacy of therapy of administration of an agonist of CTACK, which is not required by the other inventions. Invention IV requires search and consideration of attracting movement of a cell within or to the skin of a mammal and efficacy of therapy of administration of an agonist of Vic, which is not required by the other inventions. Invention V requires search and consideration of contacting cells with CTACK and identifying cells that express a receptor for CTACK, which is not required by the other inventions. Invention VI requires search and consideration of contacting cells with Vic and identifying cells that express a receptor for Vic, which is not required by the other inventions. Invention VII requires search and consideration of contacting a mammalian CTACK with a GPR2 receptor and production of a ligand:receptor complex, which is not required by the other inventions. Invention VIII requires search and consideration of contacting a mammalian Vic with a GPR2 receptor and production of a ligand:receptor complex, which is not required by the other inventions. Invention IX requires search and consideration of modulation of the physiology or development of a GPR2-expressing cell and contacting the cell to agonist of a mammalian CTACK, which is not required by the other inventions. Invention X requires search and consideration of modulation of the physiology or development of a GPR2-expressing cell and contacting the cell to agonist of a mammalian Vic, which is not required by the other inventions. Invention XI requires search and consideration of modulation of the physiology or development of a GPR2-expressing cell and contacting the cell to antagonist of a

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mammalian CTACK, which is not required by the other inventions. Invention XII requires search and consideration of modulation of the physiology or development of a GPR2-expressing cell and contacting the cell to antagonist of a mammalian Vic, which is not required by the other inventions. Invention XIII requires search and consideration of measurement of GPR2 receptor and CTACK binding in the presence and absence of a compound, which is not required by the other inventions. Invention XIV requires search and consideration of measurement of GPR2 receptor and Vic binding in the presence and absence of a compound, which is not required by the other inventions. Invention XVIII requires search and consideration of efficacy of therapy by administration of an antagonist against GPR2, which is not required by the other inventions.

- b. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups XV-XVII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group XV can be prepared by processes which are materially different from recombinant DNA expression of Group XVI, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group XVI can be used other than to make the protein of Group XV, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group XV can be used in materially different methods other than to make the antibody of Group XVII, such as in therapeutic or diagnostic methods (e.g., in screening). Finally, although the antibody of Group XVII can be used to obtain the DNA of Group XVI, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods.

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- c. Inventions XV/XVI/XVII and I-XIV/XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups XV/XVI/XVII and I-XIV are unrelated products and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I-XIV/XVIII do not recite the use or production of the polypeptide, polynucleotide, or antibody of Inventions XV, XVI, and XVII.
2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate search requirements and recognized divergent subject matter, restriction for examination purposes as indicated is proper.
3. This application contains claims directed to the following patentably distinct species of the claimed invention:
 - A method of modulating movement of a cell within or to the skin of a mammal wherein the movement is:
 - a. within said skin
 - b. chemotactic
 - c. chemokinetic

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 4 and 7-23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of modulating movement of a cell within or to the skin of a mammal wherein the cell is:

- d. a CLA+ cell
- e. a T cell
- f. a dendritic cell
- g. a dendritic cell precursor
- h. a dermal fibroblast cell
- i. a dermal endothelial cell
- j. a melanocyte

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2, 4-5, and 7-23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of modulating movement of a cell within or to the skin of a mammal, said method comprising administering an effective amount of an antagonist, wherein the antagonist is:

- k. a mutein of natural CTACK
- l. a mutein of natural Vic
- m. an antibody that neutralizes CTACK
- n. an antibody that neutralizes Vic
- o. an antibody which blocks GPR2 ligand binding

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5-13 and 16-23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of modulating movement of a cell within or to the skin of a mammal comprising administering an effective amount of an agonist, wherein the agonist is

p. CTACK

q. Vic

r. a GPR2 ligand

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-4 and 8-23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of modulating physiology or development of a GPR2 expressing cell wherein the physiology is selected from:

- s. a cellular calcium influx
- t. a chemoattractant response
- u. a cellular morphology modification response
- v. phosphoinositide lipid turnover
- w. an antiviral response
- x. an inflammatory response

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-12 and 16-20 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of testing a compound for ability to affect GPR2 receptor-ligand interaction wherein the compound is an antibody against:

y. GPR2

z. Vic

aa. CTACK

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-15 and 18-20 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of modulating movement of a cell by administering an antagonist or agonist, wherein the antagonist or agonist is administered in combination with:

- bb. an antibiotic
- cc. an analgesic
- dd. an immune suppressive therapeutic
- ee. an anti-inflammatory drug
- ff. a growth factor
- gg. an immune adjuvant

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 3, 6, and 8-23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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If Applicant selects Inventions I, II, III, or IV, one species from type of cell movement group, one species from the cell type group, and one species from the agent of combination administration group must be chosen to be fully responsive.

If Applicant selects Inventions I, II, XI, or XII, one species from the antagonist group must be chosen to be fully responsive.

If Applicant selects Inventions III or IV, one species from the agonist group must be chosen to be fully responsive.

If Applicant selects Inventions IX, X, XI, or XII, one species from the physiological response group must be chosen to be fully responsive.

If Applicant selects Inventions XIII or XIV, one species from the compound/antibody group must be chosen to be fully responsive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bridget E. Bunner
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August 12, 2002

